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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,072	05/10/2005	Andreas Van Eikeren	H01.2-11733	8652
490	7590	09/28/2007		
VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER LEWIS, RALPH A	
			ART UNIT 3732	PAPER NUMBER
			MAIL DATE 09/28/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/517,072

Applicant(s)

EIKEREN ET AL.

Examiner

Ralph A. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **Objection to the Claims**

Claims 1-3, 5-9, 13 and 15 are objected to under 37 CFR 1.75(a) for failing to particularly point out and distinctly claim the subject matter which applicant regards as his/her invention.

In the present claims the examiner is somewhat confused as to what it is that applicant is attempting to claim with the preamble "Isolation of tooth material to be treated . . . " and "Isolation according to claim 1 . . . " The examiner interprets (and has interpreted throughout the prosecution) the odd language as claiming a method, but notes that perhaps applicant is attempting to claim something different when comparison is made to claims 10-12 and 16 which clearly sets forth a "method." If applicant is attempting to claim a product (e.g. a mouth having an isolated tooth), then applicant is required to clearly state such on the record and be prepared for a nonstatutory subject matter rejection (i.e. claiming a human being). If, on the other hand, applicant is attempting to only claim the material used for isolating the tooth, then it is noted that admitted prior art materials are clearly not patentable, even if applicant intends for them to be used in a new or different manner. Clarification is required.

### **Rejections based on Prior Art**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5 and 9-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dragan (US 5,676,543).

Dragan discloses an addition reaction silicone (A-silicone)(column 3, line 25), a condensation silicone (C-silicone)(column 3, line 24) and/or polyethers (column 3, line 23) 10 that is mixed from a base portion and a catalyst portion and then "placed about the lower teeth 12, 12' and gum 14 and allowed to set" (emphasis added - column 3 lines 55-56). After the material 10 is set (cross-links in a self-cure manner) it forms an "impression 20 [that] closely conforms to the shape of the teeth 12, 12' and gum 14" (emphasis added - column 4, lines 1-3). The material 10 is removed from the patient's mouth and "filled with a layer of flowable, syringeable or less viscous material 18" (column 4, lines 7-9) which maybe any of the silicone materials used for tray 10 (note column 4, lines 23-24). The flowable material 18 is placed "to flow around the teeth 12, 12' and gum 14" (emphasis added – column 4, line 30) where it is then allowed to set before removal. Both materials 10 and 18 and their use by Dragan, meet the "covering composition" limitations and it's broadly claimed method of use.

In regard to the limitation that the material is to adhere to the patient's gingival tissue, the examiner is of the position that the Dragan material adheres (at least partially) to a patient's gingival. If applicant's C-silicone is capable of adhering to the gingival, then so is the Dragan C-silicone; the laws of physics apply equally to applicant and the prior art. Applicant discloses, nor claims, any special ingredients in the prior art C-

silicone (or A-silicone or polyethers) that make it capable of adhering to soft tissues that other such materials do not typically include.

In response to the present rejection applicant argues that Dragan discloses a method of applying material to surround the teeth and gums, but not "isolation of tooth material to be treated to protect the surrounding gums" as required by claim 1. The Dragan method retracts the gum tissue in a safe protective manner thereby isolating the tooth/teeth which is to be treated so that an accurate impression may be made and the tooth/teeth treated. Applicant's argument that the Dragan A-silicone does not adhere to the patient's gum tissue is addressed above. Finally, applicant argues that the Dragan silicone material 18 includes an astringent. The examiner directs applicant's attention to page 6 of their specification where applicant lists a page of additives that might be combined with the claimed silicone materials. The examiner understands the limitation "group consisting of A-silicones, C-silicones or polyethers" to mean that the composition must contain one of the three listed materials, but that the materials are not necessarily in their pure form – i.e. they can contain common additives as described in applicant's specification (a cup of coffee is still a cup of coffee even if it contains cream and sugar).

Claims 1-3, 5, 9, 10, 12, 13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Amstutz et al (US 4,559,013).

Amstutz et al disclose a protective addition reaction silicone (A-silicone)(column 5, lines 14-15) that is applied to a patient's surrounding teeth and gums 7 where it cross-links and self cures to produce an elastomeric material (column 5, lines 20-30).

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The composition is a two-component system that is mixed together (column 5, lines 9 and 10).

In regard to the limitation that the material adheres to the gingival it is noted that such adherence is inherent in the Amstutz et al method. As with applicant's A-silicone material, the Amstutz et al A-silicone material inherently adheres at least partially to the patient's gums. The laws of physics apply to everyone.

In response to the present rejection applicant argues that the Amstutz et al material covers teeth and braces, not "surrounding gum to protect it from aggressive dental treatment means applied to isolated tooth material." The examiner disagrees, the Amstutz et al material clearly is formed to cover the gums – see the material at numerals 8 and 12 in Fig 4 that covers the gums. Moreover, the formed material is designed protect the gums and soft tissues from the isolated aggressive dental treatment means – i.e. the braces. Applicant reads much more into the claims than what the broad claim language calls for.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan (US 5,676,543).

Adjusting the ingredients so that the setting times fall within the ranges claimed would have been obvious to one of ordinary skill in the art as a matter of routine in practicing the Dragan invention. The use of a common prior art double barrel syringe to provide for such storage and mixing would have been obvious to one of ordinary skill in the art.

Claims 6-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amstutz et al (US 4,559,013).

Adjusting the ingredients so that the setting times fall within the ranges claimed would have been obvious to one of ordinary skill in the art as a matter of routine in practicing the Amstutz et al invention. The use of a common prior art double barrel syringe to provide for such storage and mixing would have been obvious to one of ordinary skill in the art.

#### **Action Made Final**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not


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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (571) 273-8300. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Cris Rodriguez, can be reached at (571) 272-4964.

R.Lewis  
September 20, 2007

  
Ralph A. Lewis  
Primary Examiner  
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